



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

MAY 19 2006

Re: Cialis  
Docket No.: 2004E-0413

The Honorable Jon Dudas  
Under Secretary of Commerce for Intellectual Property and  
Director of the United States Patent and Trademark Office  
Box Pat. Ext.  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 5,859,006, filed by ICOS Corporation, under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Cialis, the human drug product claimed by the patent.

The total length of the regulatory review period for Cialis is 1,943 days. Of this time, 1,067 days occurred during the testing phase and 876 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: July 29, 1998.

FDA has verified the applicant's claim that the date the investigational new drug application became effective was on July 29, 1998.

2. The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act: June 29, 2001.

FDA has verified the applicant's claim that the new drug application (NDA) for Cialis (NDA 21-368) was initially submitted on June 29, 2001.

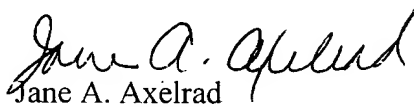
3. The date the application was approved: November 21, 2003.

FDA has verified the applicant's claim that NDA 21-368 was approved on November 21, 2003.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Jane A. Axelrad".

Jane A. Axelrad

Associate Director for Policy  
Center for Drug Evaluation and Research

cc: James J. Napoli  
Marshall, Gerstein & Borum, LLP  
6300 Sears Tower  
233 South Wacker Drive  
Chicago, IL 60606